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FEB 0 5 2002

510(k) SUMMARY

Preparation Date: January 04, 2002

1.0 Company Information

Manufacturer: Timm Medical Technologies, Inc.
6585 City West Parkway
Eden Prairie, MN 55344

Contact: Mr. Chris Hadland
952-562-3972 tel
952-947-9411 fax

No sterilization is performed at this facility.

2.0 Device Modified

Trade Name: ErecAid® Classic System
ErecAid® Esteem® Manual System
ErecAid® Esteem® Battery System

Common Name: Vacuum Erection Device

Classification: External Penile Rigidity Device
Not classified

3.0 Intended Use

The Classic and Esteem vacuum systems are intended to artificially produce an erection in males suffering from erectile dysfunction (impotence) in order to facilitate sexual intercourse. A vacuum is applied to the penis, causing it to become erect and rigid as blood is drawn into the corpora cavernosa. A constriction ring is then placed on the base of the penis to restrict venous blood flow out of the penis. The device is intended to be used at home or in a doctor's office or clinic.

4.0 Device Modifications

The silicone Freedom Ring™ was developed as an alternative constriction ring for the ErecAid Classic and Esteem vacuum erection devices. It is similar to the existing polyisoprene Pressure-Point™ Ring (PPR) in that it contains both a urethral notch and dorsal pressure points. It is designed to deliver the same sealing pressure to the penis, thus preventing escape of blood after an erection is achieved. The Freedom Ring makes the vacuum seal against the base of the penis rather than against the groin, thereby reducing the probability of scrotal tissue or pubic hair entrapment.

When using the Pressure-Point Ring, it must be stretched over the proximal end of the cylinder. For Esteem users, the optional Easy Action ring loader cone is offered for this purpose. Classic users must accomplish this task manually. Once an erection is achieved, the lubricated ring is slipped off the cylinder onto the base of the penis. This transferal often results in an uncomfortable "snapping" effect on the penis.

The Freedom Ring eliminates this discomfort as there is no transferal process. The patient puts the ring on the cylinder, places the lubricated penis in the ring opening, and begins the pumping action. The head of the penis is drawn into the ring as the vacuum is created. The Easy Action ring loader cannot be used with the new Freedom Ring.

5.0 Performance Tests

Continued safety and efficacy of the ErecAid Classic and Esteem vacuum erection systems, while using the new Freedom constriction ring, were demonstrated through bench tests. Physical properties and dimensions of the new Freedom Ring were compared to those of the corresponding sizes of Pressure-Point Ring. The pressure exerted on the penis by each Freedom Ring was verified to be comparable to that of the corresponding size PPR.

In addition, bench testing was conducted to demonstrate that the Classic and Esteem systems continued to meet documented product specifications regarding initial vacuum seal, and maximum vacuum pressure and leak rate.

6.0 Clinical Studies

No clinical study was required to demonstrate safety or effectiveness of the new Freedom constriction ring when used with either the ErecAid Classic or Esteem vacuum erection system.

7.0 Conclusion

Timm Medical Technologies, Inc. believes that the new Freedom constriction ring introduces no new issues of safety or efficacy with respect to the ErecAid Classic and Esteem vacuum erection systems. It was designed to provide increased patient comfort and ease of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

Mr. Chris Hadland
VP, Quality and Regulatory Affairs
Timm Medical Technologies, Inc.
6585 City West Parkway
EDEN PRAIRIE MN 55344

Re: K020082
Trade/Device Name: ErecAid® Classic System
ErecAid® Esteem® Manual System
ErecAid® Esteem® Battery System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LKY
Dated: January 7, 2002
Received: January 10, 2002

Dear Mr. Hadland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K020082

Device Name: ErecAid® Classic System
ErecAid® Esteem® Manual System
ErecAid® Esteem® Battery System

Indications for Use:

The Classic and Esteem vacuum systems are intended to artificially produce an erection in males suffering from erectile dysfunction (impotence) in order to facilitate sexual intercourse. A vacuum is applied to the penis, causing it to become erect and rigid as blood is drawn into the corpora cavernosa. A constriction ring is then placed on the base of the penis to restrict venous blood flow out of the penis. The device is intended to be used at home or in a doctor's office or clinic.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020082